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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,095	04/13/2004	Eiichi Ueda	KON-1870	6153

20311 7590 08/02/2007
LUCAS & MERCANTI, LLP
475 PARK AVENUE SOUTH
15TH FLOOR
NEW YORK, NY 10016

EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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08/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/824,095

Applicant(s)

UEDA ET AL.

Examiner

Melissa Perreira

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-26 are pending in the application. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

Response to Arguments

1. Applicant's arguments filed 7/13/07 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-18 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mackaness et al. (US 4,192,859) in view of Otake et al. (US2004/0099976A1) or Castor (US 5,554,382) in further view of Na et al. (US 5,326,552) as stated in the office action mailed 5/17/07.
4. Applicant asserts that Mackaness et al., Otake et al. and Castor teach the use of organic solvents in the preparation of their materials.
5. The examiner concedes that the reference of Mackaness et al. does include organic solvents but this reference was not utilized to teach the preparation of liposomes without organic solvents. The reference of Mackaness et al. was used to

teach of the inclusion of phospholipids, sterols and an amine in the preparation of liposomes of the iodated radiographic contrast medium.

6. The reference of Otake et al. does teach of the preparation of unilamellar liposomes via super critical carbon dioxide without the use of organic solvents. It is clearly stated that the liposomes are prepared in aqueous medium and that a cosolvent is **optionally** added (p3, [0035]). Example 1 shows the preparation of a liposome without the use of any cosolvent (p4, [0068]). Given that the abstract also states that the preparation of the liposomes is without using harmful organic solvents, it would be obvious to one skilled in the art to prepare the liposomes without the cosolvent.

7. Castor teaches the preparation of unilamellar liposomes via super critical carbon dioxide without the use of organic solvents. It is clearly stated that the liposomes are prepared in aqueous medium and that a cosolvent or entrainer is **optionally** added (i.e. with or without entrainer) (column 8, line 43; column 9, lines 29-32).

8. In combination, it would be obvious to prepare the liposomes of Mackaness et al. in a much more biocompatible fashion by utilizing the super critical carbon dioxide methods containing no organic solvents of Otake et al. or Castor.

9. Applicant asserts that Na et al. does not teach a liposome.

10. The examiner concedes that Na et al. does not teach a liposome but does teach of a nanoparticle containing a modified nonionic polyethylene glycol, polyethylene oxide or block copolymers of propylene oxide and ethylene oxide lipid surface. The surface modifier, such as PEO is used to overcome the charge effect imparted by the

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phospholipid to the particles which causes the particle to be cleared from the blood faster.

11. In combination with the references above, it would be obvious to utilize a surface modifier for the liposomes to provide liposomes with targeted site-specificity and images of exceptional resolution and to control the interfacial tension between the phospholipids solution and water to facilitate the generation of the liposome vesicle with the desired particle size.

12. Applicant asserts that Na et al. teaches the use of organic solvents in the preparation of the particles.

13. Na et al. explicitly states that the preferred liquid dispersion medium is water (column 3, lines 55-56).

14. It is respectfully pointed out that instant claim 2,9 and 17-20 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

15. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klaveness et al. (US 5,676,928) in view of Otake et al. (US2004/0099976A1) or Castor

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(US 5,554,382) in further view of Na et al. (US 5,326,552) as stated in the office action mailed 5/17/07.

16. Applicant asserts that Klaveness et al., Otake et al. and Castor teach the use of organic solvents in the preparation of their materials.

17. The examiner concedes that the reference of Klaveness et al. does include organic solvents but this reference was not utilized to teach the preparation of liposomes without organic solvents. The reference of Klaveness et al. was used to teach of the inclusion of phospholipids, stabilizing agents, etc. for the preparation of the unilamellar liposomes of the iodated radiographic contrast medium.

18. The reference of Otake et al. does teach of the preparation of unilemellar liposomes via super critical carbon dioxide without the use of organic solvents. It is clearly stated that the liposomes are prepared in aqueous medium and that a cosolvent is **optionally** added (p3, [0035]). Example 1 shows the preparation of a liposome without the use of any cosolvent (p4, [0068]). Given that the abstract also states that the preparation of the liposomes without using harmful organic solvents, it would be obvious to one skilled in the art to prepare the liposomes without the cosolvent.

19. Castor teaches the preparation of unilamellar liposomes via super critical carbon dioxide without the use of organic solvents. It is clearly stated that the liposomes are prepared in aqueous medium and that a cosolvent or entrainer is **optionally** added (i.e. with or without entrainer) (column 8, line 43; column 9, lines 29-32).

20. In combination, it would be obvious to prepare the liposomes of Klaveness et al. in a much more biocompatible fashion by utilizing the super critical carbon dioxide methods containing no organic solvents of Otake et al. or Castor.

21. Applicant asserts that Na et al. does not teach a liposome.

22. The examiner concedes that Na et al. does not teach a liposome but does teach of a nanoparticle containing a modified nonionic polyethylene glycol, polyethylene oxide or block copolymers of propylene oxide and ethylene oxide lipid surface. The surface modifier, such as PEO is used to overcome the charge effect imparted by the phospholipid to the particles which causes the particle to be cleared from the blood faster.

23. In combination with the references above, it would be obvious to utilize a surface modifier for the liposomes to provide liposomes with targeted site-specificity and images of exceptional resolution and to control the interfacial tension between the phospholipids solution and water to facilitate the generation of the liposome vesicle with the desired particle size.

24. Applicant asserts that Na et al. teaches the use of organic solvents in the preparation of the particles.

25. Na et al. explicitly states that the preferred liquid dispersion medium is water (column 3, lines 55-56).

26. It is respectfully pointed out that instant claim 2,9 and 17-20 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The

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patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

Double Patenting

27. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

28. Claims 21,22 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4,6 and 8-10 of copending Application No. 11/180849 as stated in the office action mailed 5/17/07.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant proposes to wait to respond to the rejection until there is an indication of allowable material and therefore the rejection is maintained.

29. Claims 21,22 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,5-7,11,12 and 14-17 of copending Application No. 11/187,397 as stated in the office action mailed 5/17/07.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant proposes to wait to respond to the rejection until there is an indication of allowable material and therefore the rejection is maintained.

Conclusion

No claims are allowed at this time.

30. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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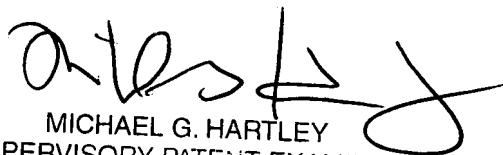
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
July 24, 2007


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER